

CLAIMS:

1. A polynucleotide that encodes a 20P2H8 polypeptide, wherein the polynucleotide is selected from the group consisting of:
 - 5 (a) a polynucleotide having the sequence as shown in FIG. 1 (SEQ ID NO: 1), wherein T can also be U;
 - (b) a polynucleotide having the sequence as shown in FIG. 1 (SEQ ID NO: 1), from about nucleotide residue number 450 through about nucleotide residue number 2000, wherein T can also be U;
 - 10 (c) a polynucleotide encoding a 20P2H8 polypeptide whose sequence is encoded by the cDNA contained in the plasmid deposited with American Type Culture Collection as Accession No. 207151;
 - (d) a polynucleotide encoding a 20P2H8 protein having the amino acid sequence shown in FIG. 1 (SEQ ID NO: 2); and
 - 15 (e) a polynucleotide that is fully complementary to a polynucleotide of any one of (a)-(d).
2. A polynucleotide that encodes a polypeptide that is at least 90% identical to the amino acid sequence shown in FIG. 1 (SEQ ID NO: 2) over its entire length.
3. A fragment of a polynucleotide of claim 1 comprising:
 - 20 (a) a polynucleotide having the sequence as shown in FIG. 1 (SEQ ID NO: 1), from nucleotide residue number 600 through about nucleotide residue number 3600;
 - (b) a polynucleotide that is a fragment of the polynucleotide of (a) that is at least 20 nucleotide bases in length; or
 - 25 a polynucleotide that selectively hybridizes under stringent conditions to the polynucleotide of (a) or (b).

4. A polynucleotide that encodes a 20P2H8 polypeptide, wherein the polypeptide includes an amino acid sequence selected from the group consisting of NYTA at residues 436-439 (SEQ ID NO: 2), NLSG at residues 459-462 (SEQ ID NO: 2), SKME at residues 56-59 (SEQ ID NO: 2), SDQD at residues 77-80 (SEQ ID NO: 2), TGED at residues 141-144 (SEQ ID NO: 2), TSNE at residues 152-155 (SEQ ID NO: 2), TAEF at residues 178-181 (SEQ ID NO: 2), TYPD at residues 203-206 (SEQ ID NO: 2), TAAE at residues 245-248 (SEQ ID NO: 2), TIED at residues 297-300 (SEQ ID NO: 2), SAEF at residues 364-367 (SEQ ID NO: 2), GLNIAK at residues 87-92 (SEQ ID NO: 2), GAALCL at residues 94-99 (SEQ ID NO: 2), GGTSNE at residues 150-155 (SEQ ID NO: 2), GLPFTA at residues 172-177 (SEQ ID NO: 2), GGKEGI at residues 194-199 (SEQ ID NO: 2), GLPYAA at residues 291-296 (SEQ ID NO: 2), GGTLNR at residues 374-379 (SEQ ID NO: 2), GSPNSL at residues 446-451 (SEQ ID NO: 2), GLAYNT at residues 475-480 (SEQ ID NO: 2), GLIHTN at residues 499-504 (SEQ ID NO: 2), QGRR at residues 102-105 (SEQ ID NO: 2), LGKR at residues 234-237 (SEQ ID NO: 2), FLGEFATDI (SEQ ID NO: 17), VLFACEEYA (SEQ ID NO: 18), LLGKRYIEL (SEQ ID NO: 19), QQFVPPTNV (SEQ ID NO: 20), CSAEEMNFV (SEQ ID NO: 21), FLSKENQVI (SEQ ID NO: 22), SLGYFPTAA (SEQ ID NO: 23), TLPKEWVC (SEQ ID NO: 24), YTFPAPAAV (SEQ ID NO: 25) and YQYATEDGL (SEQ ID NO: 26).
5. A polynucleotide of claim 1 that is labeled with a detectable marker.
6. A recombinant expression vector that contains a polynucleotide of claim 1.
7. A host cell that contains an expression vector of claim 6.
8. A process for producing a 20P2H8 polypeptide comprising culturing a host cell of claim 7 under conditions sufficient for the production of the polypeptide.
9. The process of claim 8, further comprising recovering the 20P2H8 polypeptide so produced.
10. A 20P2H8 polypeptide produced by the process of claim 8.
11. A 20P2H8 polypeptide encoded by the polynucleotide of claim 1.

12. A polypeptide comprising at least 15 contiguous amino acids of the polypeptide of claim 11.
13. An antibody or fragment thereof that specifically binds to the 20P2H8 polypeptide of claim 11.
- 5 14. The antibody or fragment thereof of claim 13, which is monoclonal.
15. A recombinant protein comprising the antigen binding region of a monoclonal antibody of claim 14.
16. The antibody or fragment thereof of claim 13, which is labeled with a detectable marker.
- 10 17. The antibody or fragment thereof of claim 16, wherein the detectable marker is selected from the group consisting of a radioisotope, fluorescent compound, bioluminescent compound, chemiluminescent compound, metal chelator or enzyme.
18. The antibody fragment of claim 13, which is an Fab, F(ab')₂, Fv or sFv fragment.
19. The antibody or fragment thereof of claim 13, which is a human antibody.
- 15 20. The antibody or fragment thereof of claim 13, which is conjugated to a toxin or a therapeutic agent.
21. The antibody of claim 13, which comprises murine antigen binding region residues and human antibody residues.
22. A transgenic animal producing a monoclonal antibody of claim 14.
- 20 23. A hybridoma producing a monoclonal antibody of claim 14.
24. A single chain monoclonal antibody that comprises the variable domains of the heavy and light chains of a monoclonal antibody of claim 14.
25. A vector comprising a polynucleotide encoding a single chain monoclonal antibody of claim 24.
- 25 26. An assay for detecting the presence of a 20P2H8 protein in a biological sample comprising contacting the sample with an antibody or fragment thereof or

recombinant protein of claim 16, and detecting the binding of 20P2H8 protein in the sample thereto.

27. An assay for detecting the presence of a 20P2H8 polynucleotide in a biological sample, comprising

- 5 (a) contacting the sample with a polynucleotide probe that specifically hybridizes to the polynucleotide of claim 1; and
- (b) detecting the presence of a hybridization complex formed by the hybridization of the probe with 20P2H8 polynucleotide in the sample, wherein the presence of the hybridization complex indicates the presence of
- 10 20P2H8 polynucleotide within the sample.

28. An assay for detecting the presence of 20P2H8 mRNA in a biological sample comprising:

- (a) producing cDNA from the sample by reverse transcription using at least one primer;
- 15 (b) amplifying the cDNA so produced using 20P2H8 polynucleotides as sense and antisense primers to amplify 20P2H8 cDNAs therein;
- (c) detecting the presence of the amplified 20P2H8 cDNA,

wherein the 20P2H8 polynucleotides used as the sense and antisense probes are capable of amplifying the 20P2H8 cDNA contained within the plasmid deposited with American Type Culture Collection as Accession No. 207151.

20

29. A method of examining a biological sample for evidence of dysregulated cellular growth comprising comparing the status of 20P2H8 in the biological sample to the status of 20P2H8 in a corresponding normal sample, wherein alterations in the status of 20P2H8 in the biological sample are associated with dysregulated cellular growth.

25

30. A method of identifying evidence of a neoplasm in a biological sample comprising:

Sub
A1

Sub
A1

5

- (a) examining a level of 20P2H8 gene expression in a test biological sample; and
 - (b) comparing the level of 20P2H8 gene expression in the test biological sample to a level of 20P2H8 gene expression found in a comparable normal biological sample,
- wherein differences in the level of 20P2H8 gene products in the test biological sample relative to the normal biological sample are associated with the neoplasm.

10

31. A method of monitoring 20P2H8 gene products comprising determining the status of 20P2H8 gene products expressed by cells in a test tissue sample from an individual and comparing the status so determined to the status of 20P2H8 gene products in a corresponding normal sample, the presence of aberrant 20P2H8 gene products in the test sample relative to the normal sample providing an indication of dysregulated cell growth within the individual.

15

32. A method of diagnosing the presence of cancer in an individual comprising:
- (a) determining the level of 20P2H8 mRNA expressed in a test sample obtained from the individual; and
 - (b) comparing the level so determined to the level of 20P2H8 mRNA expressed in a comparable known normal tissue sample,
- the presence of elevated 20P2H8 mRNA expression in the test sample relative to the normal tissue sample providing an indication of the presence of cancer.

20

33. A method of diagnosing the presence of cancer in an individual comprising:
- (a) determining the level of 20P2H8 protein expressed in a test sample obtained from the individual; and
 - (b) comparing the level so determined to the level of 20P2H8 protein expressed in a comparable known normal tissue sample,
- the presence of elevated 20P2H8 protein in the test sample relative to the normal tissue sample providing an indication of the presence of cancer.

25

Sub
A3

34. The method of claim 32, wherein the cancer is prostate, cervical, kidney, stomach, skin, pancreatic, colon, bladder, breast, lung, testicular or ovarian cancer, and the test and normal tissue samples are selected from the group consisting of prostate tissue, kidney tissue, cervical tissue, skin tissue, stomach tissue, colon tissue, bladder tissue, breast tissue, lung tissue, pancreatic tissue, rectal tissue, ovarian tissue, testicular tissue, lymphatic tissue, serum, blood or semen.
35. A pharmaceutical composition comprising a 20P2H8 polypeptide of claim of claim 11 or an immunogenic portion thereof, and a physiologically acceptable carrier.
36. A pharmaceutical composition comprising the vector of claim 25, and a physiologically acceptable carrier.
37. A pharmaceutical composition comprising an antisense polynucleotide complementary to or a ribozyme capable of cleaving a polynucleotide of claim 1, and a physiologically acceptable carrier.
38. A pharmaceutical composition comprising an antibody or fragment thereof of claim 13, and a physiologically acceptable carrier.
39. A method of treating a patient with a cancer that expresses 20P2H8 which comprises administering to said patient a vector according to claim 25, such that the vector delivers the single chain monoclonal antibody coding sequence to the cancer cells and the encoded single chain antibody is expressed intracellularly therein.
40. A method of treating a patient with a cancer that expresses 20P2H8 which comprises administering to said patient a composition of claim 37.
41. A vaccine composition for the treatment of a cancer expressing 20P2H8 comprising an immunogenic portion of a 20P2H8 protein and a physiologically acceptable carrier.
42. A method of inhibiting the development of a cancer expressing 20P2H8 in a patient, comprising administering to the patient an effective amount of the vaccine composition of claim 40.

43. A method of identifying a molecule that modulates a biological activity of 20P2H8 comprising:

- (a) contacting a molecule with a cell that expresses 20P2H8;
- (b) assaying a biological activity of 20P2H8 in the presence and absence of the molecule; and
- (c) determining whether the biological activity of 20P2H8 is altered by the presence of the molecule, an alteration in the biological activity of 20P2H8 being indicative of a molecule that modulates a biological activity of 20P2H8.

5

ADD
Att

10